REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance.

Claims 1-10, 13-22 and 35-41 are pending in the application.

Claims 2, 3, 4, 5, and 6 have been amended to recite that the formulation comprises "EPA" in free acid form.

Claim 8 is amended so that it is no longer a multiple dependent claim. Claim 8 is now solely dependent on claim 1.

Claims 35 and 36 are amended to delete the term "calculating" for the term "measuring". Applicants respectfully submit that the term "measuring" is more consistent with the language used in the specification. For example, the term "measured" is explicitly recited in paragraph [0036] of the published application, whereas the terms "calculating" and "calculated" are not found in the specification. In view of the above, Applicants respectfully submit that the term "measuring" is better supported by the present disclosure.

New claims 38-41 have been added. The original claims and present specification at page 10, lines 10-20 and page 11, lines 5-15 supports the addition of claims 38-41.

Applicants respectfully submit that no new matter has been added to the disclosure.

Claims 1-10, 13-22 and 35-37 stand rejected under 35 USC §103(a) as allegedly being obvious BREIVIK in view of BORKAN et al. This rejection is traversed.

BREIVIK discloses a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-

eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids (see abstract). The fatty acid composition is derived from a marine oil raw material such as fish oil (col. 3, lines 24-26). BREIVIK indicates that the composition can be delivered in the form a soft gelatin capsule (col. 6, lines 55 -60).

In an effort to remedy the deficiencies of BREIVIK, the Official Action cites to BORKAN.

BORKAN discloses a chewable, edible soft gelatin capsule comprising a shell containing water, gelatin, plasticizer, and an amount of hydrogenated starch hydrolysate effective to render the shell dispersible and soluble in the mouth of the user (abstract). The starting gelatin material used in the manufacture of capsules is obtained by the partial hydrolysis of collagenous material, such as the skin, white connective tissues, or bones of animals.

BORKAN states that Type A gelatin is derived mainly from porcine skins by acid processing, and exhibits an isoelectric point between pH 7 and pH 9, while Type B gelatin is derived from alkaline processing of bones and animal (bovine) skins and exhibits an isoelectric point between pH 4.7 and pH 5.2 (col. 3, lines 20-35).

Applicants respectfully submit that one skilled in the art would lack the motivation to combine and modify the publications in a manner that would result in the claimed invention, as there is no discussion in BREIVIK or BORKAN of the stability of soft gelatin capsules containing a free acid form omega-3 fatty acid composition.

Starting from BREIVIK, the skilled person has no teaching that there may be a problem with the stability and shelf life of soft Type B gelatin capsules containing a free omega-3 polyunsaturated fatty acid composition. Without specific investigation into the

comparative stabilities of corresponding Type A and Type B soft gelatin capsules, the skilled person would have had no idea that there was a stability issue to be resolved. "A patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This *part* of the "subject matter as a whole" should always be considered in determining the obviousness of the invention under 35 USC § 103." See *In re Sponnoble*, 405 F. 2d 578, 160 USPQ 237 (CCPA 1969). [Where] there is no evidence of record that a person of ordinary skill in the art at the time [an applicant's] invention would have expected [a problem],...it is not proper to conclude that [an invention], which solves the problem...would have been obvious to that hypothetical person of ordinary skill in the art. See *In re Momiya,* 509 F. 2d 566, 572, 184 USPQ 607, 612 (CCPA 1975). Since BREIVIK does not discuss the stability over time of soft gelatin capsules containing a free omega-3 fatty acid composition, the person of ordinary skill in the art on reading BREIVIK would not be aware that the problem addressed by the present invention even needed to be solved in the first place.

The person of ordinary skill in the art would have needed motivation to consider combining the teachings of BRIEVIK and BORKAN in the manner suggested by the Examiner. "The citing of a reference that merely indicate[s] that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." See *Ex parte* Hiyamizu, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note *In re* Dembiczak 175 F. 3d 994, 999 (Fed. Cir. 1999). "[A] patent composed of several elements is not

proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense dictates one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be **important** to identify **a reason** that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed new invention does. This is because **inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.**" KSR, 1727 S. Ct. 1727, at 1741 (2007) (emphasis added). A quotation acknowledging a "helpful insight" by the Court of Customs and Patent Appeals when that court first established TSM. "Often, it will be necessary for a court to look to interrelated teachings of multiple patents...**to determine whether there was an apparent reason** to combine the known elements in the fashion claimed by the patent at issue." KSR, S. Ct. at 1740-41 (emphasis added).

Furthermore, Applicants respectfully note that the problem faced by the inventors of the present application was how to produce soft gelatin capsules having adequate stability for the shelf life of the product. The solution was to use Type A gelatin for the gelatin shell. BORKAN does not address the problem of stability of a soft gelatin capsule by any means, let alone the selection of a particular type of gelatin. Therefore, one skilled in the art would have lacked the necessary motivation to turn to this reference when faced with this problem and there is nothing in this reference that would point to the solution discovered by the inventors.

Moreover, one skilled in the art would not have combined a fatty acid composition from an unpalatable marine oil raw material such as fish oil, with a readily

chewable capsule as disclosed by BORKAN. Indeed, in that omega-3 poly unsaturated fatty acids are not palatable, the skilled person would not have considered combining BREIVIK with BORKAN since the BORKAN reference is concerned exclusively with developing a readily chewable soft capsule.

In view of the above, Applicants respectfully submit that one skilled in the art would lack the necessary motivation to combine and modify the two publications.

In addition, since BORKAN does not make any reference at all to the problem of improving the stability of soft gelatin capsules, the selection of this reference to support a claim that the Applicant's solution to this problem is obvious, is based on an improper hindsight analysis with prior knowledge of the invention which, of course, would not have been available to the person of ordinary skill in the art at the priority date for this invention.

Applicants further note that even if one skilled in the art were to combine and modify the two publications, the combination would still not result in the claimed invention.

There is no recognition in either reference of a soft gelatin capsule comprising Type A gelatin that exhibits a longer shelf life as compared to a soft gelatin capsule comprising Type B gelatin as claimed. In imposing the rejection, the Official Action of February 12, 2009 states on page 5 that BORKAN is cited for the proposition that Type A gelatin and Type B gelatin are made by the same process and are "interchangeable". However, Applicants respectfully submit that the Official Action is mistaken. BORKAN plainly discloses at column 3, lines 20-39 that Type A and Type B gelatins are made by different processes, which can result in a gelatin having different properties of viscosity and bloom strength. At column 3, lines 39-44, BORKAN states that "The gelatin may be

of Type A, Type B, or a mixture thereof. Bloom numbers, the indicator of gelatin strength, may range from about 60-300." BORKAN neither discloses nor suggests a soft gelatin capsule having adequate stability for the shelf life of a product, much less the unexpected property of having adequate stability when the capsule contains a free polyunsaturated fatty acid formulation.

Without actually making soft Type A or Type B gelatin capsules containing a free polyunsaturated fatty acid formulation and measuring the disintegration time after storage of the capsules over time, it would not have been possible for one skilled in the art to deduce that the shelf life of the capsules may be improved by using Type A gelatin in place of Type B gelatin to form the capsule.

Thus, even if one skilled in the art were to combine and modify the publications, there is no indication that one skilled in the art would obtain a soft gelatin capsule as claimed.

Applicants also respectfully submit that Table 1 found on page 10 of the present specification shows that the claimed invention exhibits unexpected results. Table 1 compares the shelf life stability and disintegration properties of gelatin capsules containing omega-3 polyunsaturated fatty acids in free acid form prepared with Type A gelatin relative to Type B gelatin. The results indicate that, for the Type B gelatin capsules stored at a given temperature, there is a general increase in disintegration times as the storage time or temperature increases.

Manufacturers of medical and food products must demonstrate that a product, in combination with its packaging components, performs efficiently, safely and effectively throughout its intended shelf life.

Determining the effects of aging on a package/product in real time is a lengthy process that would severely delay market introduction of new products. Therefore, a standardized test methodology was developed to accurately evaluate the environmental effect of storage on a package/product during its expected usable shelf life.

An accelerated shelf life test subjects samples to elevated temperatures for specific periods of time to simulate the effects of real-time aging and to provide data to accurately predict the effect of real-time aging on his package/product. The results of accelerated shelf life tests that simulate the period claimed for product expiration (1 year, 2 years, etc.) usually form an important part of an application for marketing authorization in the United States or elsewhere.

Accelerated aging techniques are generally based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. This function states that a 10°C increase or decrease in the temperature of a homogenous process, results in approximately a two times or ½ time change in the rate of a chemical reaction.

In this regard, one skilled in the art would have recognized the accelerated shelf life data set forth in Table 1 in the present specification as showing that the chemical reactions involving the deterioration of gelatin and omega-3 polyunsaturated fatty acids in free acid form is unexpectedly inhibited/reduced in soft gelatin capsules produced with Type A gelatin as opposed to Type B gelatin. The result being that soft gelatin capsules containing Type A gelatin and omega-3 polyunsaturated fatty acids in free acid form exhibit improved disintegration and shelf life properties relative to capsules prepared with Type B gelatin.

For example, at 25°C, the dissolution time after 12 months increases by 43% for Type B capsules whereas the corresponding increases for Type A capsules is only 17%. In other words, the increase in dissolution time for Type B gelatin capsules is more than 2.5 times that for the Type A capsules. At 30°C, the Type B capsules are "insoluble" after 12 months, whereas the dissolution time (10 mins) for the Type A capsules is still well within 30 minutes for the product. Type B capsules perform so poorly that the difference in dissolution time for Type B gelatin capsules as compared to Type A capsules cannot even be calculated. The fact that certain tests were not performed at 9 months and 12 months in Table 1 is irrelevant because earlier tests at 3 months and 6 months already show that Type A gelatin exhibits superior disintegration and shelf life properties (see page 4 of the Official Action), one skilled in the art would have considered the results obtained at 25°C and 30°C as significant and unexpected.

The Examiner is respectfully reminded that the Patent Office must consider objective indicia of nonobviousness whenever present. Specifically, the Patent Office is bound to consider evidence of unexpected results, commercial success, long-felt but unresolved needs, failure of others, skepticism of experts. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 f. 2d 1530, 1538 (Fed Cir. 1983). Federal Circuit precedent mandates consideration of evidence already present in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F. 2d 1029 (Fed Cir. 1986). (Vacating Board decision which refused to consider data in the specification which compared an embodiment of the invention with the prior art product and noting that such evidence spoke to unexpected results and non-obviousness).

Thus, contrary to contentions of the outstanding Official Action, the results in the specification confirm that the use of a capsule comprising Type A gelatin and containing a formulation comprising omega-3 polyunsaturated fatty acids in free acid form unexpectedly provides a soft gel capsule having improved shelf stability and disintegration times.

In view of the above, applicants respectfully request that the obviousness rejection of the claims be withdrawn.

Applicants respectfully submit that claims 35-41 are even further distinguishable from the proposed combination of BREIVIK and BORKAN. Claims 35-41 explicitly recite these unexpected shelf life and disintegration properties exhibited by the invention.

For example, claim 35 recites that the soft gelatin capsule according to claim 1, wherein the shelf life is determined by storing the soft gelatin capsule comprising Type A gelatin and the soft gelatin capsules comprising Type B gelatin for 3 months at a temperature of $40^{\circ}C$; disintegrating each of the capsules in water at $37^{\circ}C$; and measuring disintegration times of each capsule to determine the shelf life of each capsule.

Claim 36 recites a soft gelatin capsule "consisting essentially" of Type A gelatin containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form.

The Official Action does not address the transitional phrase of claim 36. Applicants respectfully submit that the rejection of claim 36 is improper for this reason alone.

Nevertheless, claim 36 excludes gelatins that contain amounts of Type B gelatin (i.e., gelatin formed with an alkali pre-treatment) that would materially affect the shelf life of the capsule. Neither BREIVIK nor BORKAN disclose or suggest such a feature.

Claim 37 recites a soft gelatin capsule, comprising at least one omega-3 polyunsaturated fatty acid in free acid form, and a gelatin "consisting essentially of" Type A gelatin. Moreover, the Official Action does not address the phrase "consisting essentially of" in claim 37. Applicants respectfully submit that the rejection of claim 37 is improper for this reason alone. Claim 37 excludes gelatins that contain amounts of Type B gelatin (i.e., gelatin formed with an alkali pre-treatment) that would materially affect the shelf life of the capsule. Claim 38 recites that the gelatin of claim 37 consists of Type A gelatin.

Claims 39-41 are explicitly directed to soft gelatin capsules having the disintegration properties that result from using a gelatin such that the soft gelatin capsule has the property of disintegrating within 30 minutes in water at 37°C after being stored for 3 months at 40°C.

Neither BREIVIK nor BORKAN suggest soft gelatin capsules containing omega-3 polyunsaturated fatty acids in free acid form and having the properties recited in claims 35-41. Thus, Applicants respectfully submit that claims 35-41 are even further distinguishable from the proposed combination of BREIVIK and BORKAN.

In view of the present amendment and foregoing remarks, therefore, applicants respectfully request that the application be allowed.

Respectfully submitted,

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